DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4003]

Medical Devices; Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses.'' This draft guidance is not final nor is it in effect at this time. The purpose of this document is to provide guidance to sponsors of breast implant prostheses on important preclinical, clinical, and labeling information that should be presented in an investigational device exemptions (IDE), a premarket approval (PMA), or a product development protocol (PDP) application. This draft guidance discusses information relevant to silicone gel-filled, saline-filled, and alternative-filled breast prostheses intended for prostheses for breast augmentation, breast reconstruction following mastectomy, and revision of a failed prosthesis.

DATES: Written comments concerning this draft guidance must be received by (*insert date 90 days after date of publication in the* **Federal Register**).

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological

addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Samie N. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide guidance to sponsors of breast implant prostheses on important preclinical, clinical, and labeling information that should be presented in an IDE, PMA, or PDP application. It may also be useful in the preparation of reclassification petitions and master files.

This draft guidance discusses information relevant to silicone gel-filled, saline-filled, and alternative-filled breast prostheses intended for prostheses for breast augmentation, breast reconstruction following mastectomy, and revision of a failed prosthesis. This draft guidance does not address tissue expanders, which are unclassified devices for temporary use. Additionally, this draft guidance does not address alternative shell materials for use in breast implants.

This draft guidance is intended to combine and replace the following three individual guidances that were previously developed for silicone gel, saline, and alternative breast prostheses:

(1) ''Draft Guidance for Preparation of FDA Submissions of Silicone Gel–Filled Breast Prostheses'' (May 11, 1992); (2) ''Draft Guidance for Testing of Alternative Breast Prostheses (Non–Silicone, Gel–Filled)'' (September 1, 1994); and (3) ''Draft Guidance for Preparation of PMA Applications for Silicone Inflatable (Saline) Breast Prostheses'' (January 18, 1995).

In addition, this draft guidance involves the revisiting and updating of the scientific preclinical and the clinical and labeling information described in those guidances.

II. Significance of Guidance

This guidance document represents the agency's current thinking on preclinical, clinical, and labeling information for breast prostheses. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance document consistent with GGP's.

III. Electronic Access

In order to receive the ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1354) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the draft guidance entitled ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Guidance on Preclinical and Clinical Data and Labeling for Breast Prostheses'' also will be available at http://www.fda.gov/cdrh/ode/1354.pdf.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found

in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/21/99
September 21, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Linda S. Kahan
Deputy Director for
Regulations Policy
Center for Devices and
Radiological Health

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

BILLING CODE 4160–01–F